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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/622,124 | 07/18/2003 | Martin F. Bachmann | 1700.0340001/BJD/SJE | 3313 |
| 26111 | 7590 | 04/16/2008 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. | | | BOESEN, AGNIESZKA | |
| 1100 NEW YORK AVENUE, N.W. | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20005 | | | 1648 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/622,124 | BACHMANN ET AL. |
| | Examiner | Art Unit |
| | Agnieszka Boesen | 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 January 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 63, 68-76, 78-88, 94, 95, 97-133 is/are pending in the application.
- 4a) Of the above claim(s) 74,99,105-107,111-113,121-123 and 133 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 63,68-73,75,76,78-88,94,95,97, 98, 100-104,108-110,114-120 and 124-132 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/24/2007.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 25, 2008 has been entered.

Claims 1-3, 15, 19, 21-34, 55, 64-67, 77, 89-93 and 96 are canceled. New claims 97-133 have been added. Claims 63 and 82 have been amended. Claims 74, 99, 105-107, 111-113, 121-123 and 133 are withdrawn as being drawn to the non-elected invention. Claims 63, 68-73, 75, 76, 78-88, 94, 95, 97-104, 108-110, 114-120, and 124-132 are under consideration in this Action. Rejections of canceled claims are moot.

Election/Restriction

New claims 105-107, 111-113, 121-123 and 133 recite the non-elected species of ghrelin peptide. The species of ghrelin peptide of SEQ ID NO: 31, SEQ ID NO: 65 and SEQ ID NO: 119 and the RNA bacteriophage of SEQ ID NO: 4 were elected and examined on the merits. Because no generic claim has been indicated allowable the Office will not search additional species of the ghrelin peptide or the RNA bacteriophage at this time. Therefore claims 74, 99, 105-107, 111-113, 121-123 and 133 are withdrawn as being drawn to the non-elected species. Claim 133 is withdrawn as being drawn to the non-elected invention.

Claim Rejections - 35 USC § 103

Rejection of claims 63, 76, 78-85, and 91-95 under 35 U.S.C. 103(a) as being unpatentable over Sebbel et al., (US Patent 6,964,769 B2, herein, “Sebbel”) in view of Kojima et al (Nature, 1999, herein, “Kojima”) **is withdrawn** in view of Applicant’s arguments.

Rejection of claims 63, 68-70, 72, 73, 75, and 85 under 35 U.S.C. 103(a) as being unpatentable over Sebbel et al., (US Patent 6,964,769 B2, herein, “Sebbel”) in view of Kojima et al (Nature, 1999, herein, “Kojima”) as applied to claims 1-3, 19, 21-30, 32-34, 55, 63, 64, and 77-84 above, and further in view of Vasiljeva et al. (FEBS Letters, 1998) and Maita et al. (Gen Pept Accession VCBPQB, 1971) **is withdrawn** in view of Applicant’s arguments.

However a new rejection is made in view of newly found prior art references.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 63, 68-73, 75, 76, 78-88, 94, 95, 97, 98, 100-104, 108-110, 114-120, and 124-132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockley et al. (US Patent 6,159,728) in view of Deghengi et al. (US 2002/0187938) and further in view of Kojima et al. (Nature, 1999 Vol. 402, p. 656-660) and Maita et al. (Gen Pept Accession VCBPQB, 1971).

Stockley teaches pharmaceutical compositions comprising virus like particles of an RNA bacteriophage, particularly the Q β bacteriophage as an antigen delivery system (see the entire

document, particularly claims 1-12). Stockley teaches the non-peptide covalent coupling between the RNA bacteriophage and the antigen of interest (see column 3, lines 22-44, column 12, lines 8-29 and claim 8). Stockley does not teach the presently claimed SEQ ID NO: 4 representing the Q β bacteriophage. Maita cures this deficiency in that Maita teaches coat protein of Q β bacteriophage having a sequence identical with present SEQ ID NO: 4 (see page 2 of Maita's reference). Neither Stockley nor Maita teach that the peptide to be delivered is a ghrelin peptide.

Deghenghi teaches administration of ghrelin peptides in a mammal to reduce the growth hormone release (see the entire document, particularly claims 1-18 and Examples 1-3). The ghrelin peptide sequences disclosed by Deghenghi comprise presently claimed SEQ ID NO: 119 (see Example 1 and claims 1, 2, and 11). Deghenghi does not teach ghrelin peptides of SEQ ID NO: 31 and SEQ ID NO: 65. Kojima cures this deficiency in that Kojima teach a human ghrelin peptide, which sequence is identical with the instantly claimed SEQ ID NO: 31 (see page 658, Figure 4, ghrelin sequence is boxed). The ghrelin peptide of SEQ ID NO: 65, with the second attachment site, is exactly the same peptide as SEQ ID NO: 31 except that peptide of SEQ ID NO: 65 has an additional cysteine residue on the amino terminus. It is herein interpreted that the cysteine residue on the C terminal of the ghrelin peptide serves as the attachment site.

It is noted that the person of ordinary skill in the art would have been motivated to provide a ghrelin peptide that lacks an n-octanoyl modification (present claim 85) for the purpose of making a construct of a core particle and an antigenic determinant. Kojima teach that ghrelin peptide purified from human stomach extract has an n-octanoyl modification (see page 658, second paragraph on the left column). The person of ordinary skill in the art would not include the n-octanoyl modification in the synthetically made ghrelin peptide because such modification

is not necessary for the peptide to be immunogenic, which is the purpose of the current invention is.

Thus it would have been *prima facie* obvious to the person of ordinary skill in the art to provide Stockley's pharmaceutical composition comprising the RNA Q β bacteriophage covalently coupled to Deghenghi's and/or Kojima's ghrelin peptide as an antigenic determinant, because Stockley teach that RNA Q β bacteriophages serve as efficient delivery systems for foreign antigens and because Deghenghi teaches administration of ghrelin peptides for therapeutic purposes.

One would have been motivated to use virus like particle of an RNA bacteriophage for delivery of ghrelin peptides because the RNA Q β bacteriophage was known as an efficient antigen delivery system for foreign antigens at the time of the present invention.

One would have had a reasonable expectation of success to make a Stockley's composition comprising Kojimas' ghrelin peptide because such constructs are routinely made in the art using methods of recombinant DNA technology.

Therefore the present claims would have been obvious to those skilled in the art at the time of the present invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen, Ph.D./
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648